

### **REMARKS**

Claim 21 is currently amended and pending in the present application. Claims 22-28 have been canceled without prejudice or disclaimer of the subject matter contained therein.

In view of the following remarks, Applicants respectfully request that the Examiner reconsider and withdraw the outstanding rejection and allow the claim pending in this application.

#### **1. Rejection of Claims 21-28 under 35 U.S.C. §112, 1<sup>st</sup> paragraph**

The Official Action states that claims 21-28 are rejected under 35 U.S.C. §112, 1<sup>st</sup> paragraph for lack of enablement. In particular, the Official Action states that claims 21-28 do not comply with the scope of the enablement requirement of 35 U.S.C. 112, first paragraph, "because the specification, while being enabling for treating SAE with Sildenafil (sic) does not reasonably provide enablement for treating SAE with any other PDEV inhibitor, nor does it provide enablement for the prophylaxis of SAE with Sildenafil (sic) or any other PDEV inhibitor."

### **RESPONSE**

Regarding the rejection of claims 22-28, Applicants respectfully point out that these claims have been canceled without prejudice or disclaimer, rendering the basis for this claim moot.

Regarding the rejection of claim 21, Applicants respectfully traverse this rejection. However, solely to overcome the instant rejection, Applicants have amended

claim 21 to recite the claim limitations that the Examiner has conceded are enabled. In particular, Applicants have amended claim 21 to recite the PDE5 inhibitor “5-[2-ethoxy-5-(4-methyl-1-piperazinylsulphonyl)phenyl]-1-methyl-3-n-propyl-1,6-dihydro-7H-pyrazolo[4,3-d]pyrimidin-7-one (sildenafil), a pharmaceutically acceptable salt thereof, or a solvate of a pharmaceutically acceptable salt thereof”. Further, Applicants have limited claim 21 to the elected disorder “sepsis associated encephalopathy” to be commensurate in scope with the elected subject matter. Further, Applicants have limited claim 21 to a method of treatment, thus deleting the phrase “or prophylaxis” from this claim.

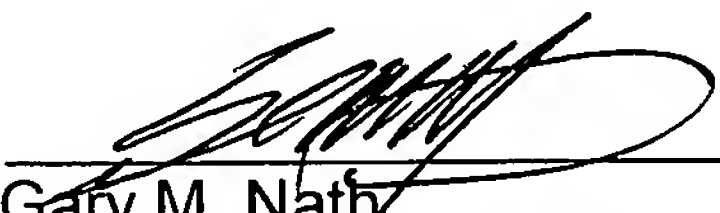
Accordingly, claim 21 complies with the requirements of 35 U.S.C. §112, 1<sup>st</sup> paragraph and is in condition for allowance. As such, applicants respectfully request that the Examiner reconsider and withdraw this rejection of pending claim 21.

**CONCLUSION**

In view of the foregoing, applicants respectfully request that the Examiner withdraw the pending rejection and allow pending claim 21 to proceed to grant. If the Examiner has any questions or wishes to discuss this matter, he is welcomed to telephone the undersigned attorney.

Respectfully submitted,  
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